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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/503,387

02/14/2000

Samantha J. Busfield

MBIO99-057CP2RCM

6531

30405

7590

08/24/2006

MILLENNIUM PHARMACEUTICALS, INC.  
40 Landsdowne Street  
CAMBRIDGE, MA 02139

EXAMINER
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HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/503,387	<b>Applicant(s)</b> BUSFIELD ET AL.	
	<b>Examiner</b> Phuong Huynh	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-29, 33-47, 53, 54, 65-79 and 87-90 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 26-29, 33-47, 53-54, 65-79, and 87-90 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 26-29, 33-47, 53-54, 65-79 and 87-90 are pending.
2. In view of the amendment filed 6/2/06, the following rejections remain.
3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 26-29, 33-47, 53-54, 65-79, and 87-90 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 44-58 of copending Application No. 10/850,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus of antibody including humanized, monoclonal, polyclonal, human antibody, single chain, antibody binding fragment thereof and conjugated antibody thereof that binds to a polypeptide comprising SEQ ID NO: 3 (human platelet glycoprotein VI), and a kit comprising said antibody of instant application include the

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species of antibody such as single chain, monoclonal, human, humanized antibody, single chain (scFv), Fab, F(ab')<sub>2</sub> fragment thereof, conjugated antibody thereof that binds to a polypeptide of SEQ ID NO: 3 (human platelet glycoprotein VI) wherein the antibody or antibody portion thereof comprises the specific CDRs from the heavy and light chains and a kit comprising said antibody of copending application 10/850,034. An issuance of a patent to copending application anticipates the antibody of instant application. On the other hand, an issuance of a patent to instant application would include the antibody of copending application 10/850,034. Claims 65-70 are included in this rejection because the copending application also teaches a method of making the antibody that specifically binds to glycoprotein VI (GPVI) comprising SEQ ID NO: 3 (see pages 63, 83-84, and 90-99 of 10/850,034).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants' arguments filed 6/2/06 have been fully considered but are not found persuasive.

Applicants' position is that the present application and pending applications 10/850,434 ('034 application) and 09/610,118 ('118 application) all claim priority to the same application, namely 09/345,468 ('468 application), filed June 30, 1999, now US Pat No 6,245,527. This patent has a post-GATT filing date and therefore has a patent term of twenty years from filing, i.e. the patent will expire on June 30, 2019. Any applications which are filed on or after May 29, 2000 are entitled to patent term adjustment.

Applicants submit that obviousness-type double patenting rejection is improper because the Examiner would need to use a two-way obviousness test based on the facts that the present case instead of one-way obviousness test to determine whether or not obvious-type double patenting existed. The fact of the present case is that, first, 09/503,387 has an effective filing date before that of a potentially conflicting patents. Second, the three applications mentioned above could not have been filed on the same day as the single chain antibodies had not been created as of the filing date of the present application. Third, the present application would have likely issued before the '034 application and the '118 application had there not been any delays from the USPTO to re-issue the Office Action after the grant of the petition.

In response, a terminal disclaimer is still required because the terminal disclaimer provides the common ownership provision as well as common expiration.

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Argument respected to the two-way obviousness test, the RCE filed 9/17/03 came from the old address and there is no change of address request in there before the office action mailed 11/19/03. Therefore, there is insufficient evidence that the delay was the fault of the office. For this reason, the use of One-Way test obviousness for determination of nonstatutory obviousness-type double patenting is proper.

5. Claims 26-29, 33-47, 53-54, 65-79, and 87-90 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 252 and 265-277 of copending Application No. 09/610,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus of antibody including humanized, monoclonal, polyclonal, human antibody, single chain, antibody binding fragment thereof and conjugated antibody thereof that binds to a polypeptide comprising SEQ ID NO: 3 (human platelet glycoprotein VI), and a kit comprising said antibody of instant application include the species of antibody such as single chain, monoclonal, human, humanized antibody, single chain (scFv), Fab, F(ab')<sub>2</sub> fragment thereof, conjugated antibody thereof that binds to a polypeptide of SEQ ID NO: 3 (human platelet glycoprotein VI) wherein the antibody or antibody portion thereof comprises the specific CDRs from the heavy and light chains and kit comprising said antibody of copending application 09/610,118. An issuance of a patent to copending application anticipates the antibody of instant application. On the other hand, an issuance of a patent to instant application would include the antibody of copending application 09/610,118. Claims 65-70 are included in this rejection because the copending application also teaches a method of making the antibody that specifically binds to glycoprotein VI (GPVI) comprising SEQ ID NO: 3 (see pages 56 and 86-93 of 09/610,118).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Applicants' position is that the present application and pending applications 10/850,434 ('034 application) and 09/610,118 ('118 application) all claim priority to the same application, namely 09/345,468 ('468 application), filed June 30, 1999, now US Pat No 6,245,527. This patent has a post-GATT filing date and therefore has a patent term of twenty years from filing,

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Argument respected to the two-way obviousness test, the RCE filed 9/17/03 came from the old address and there is no change of address request in there before the office action mailed 11/19/03. Therefore, there is insufficient evidence that the delay was the fault of the office. For this reason, the use of One-Way test obviousness for determination of nonstatutory obviousness-type double patenting is proper.

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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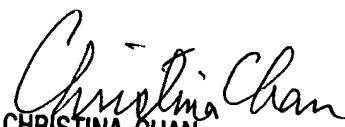
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
9. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

August 18, 2006

  
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